

## BEST AVAILABLE COPY

Appl. No. 10/759,732  
Amendment dated March 27, 2006  
Reply to Office Action of January 29, 2006

PATENT

**Amendments to the Specification:**

Please replace paragraph [0047] with the following amended paragraph:

[0047] The fascial tissue of the pelvic floor may comprise tissues referred to under different names by surgeons of different disciplines, and possibly even by different practitioners within a specialty. In fact, some surgeons may assign a collagenous support structure of the endopelvic fascia one name when viewed from a superior approach, and a different name when viewed from an inferior approach. Some of the endopelvic fascia may comprise two collagenous layers with a thin muscular layer therebetween, or may comprise a single collagenous layer. The hammock-like endopelvic fascia described herein may be damaged or missing, particularly after pregnancy, so that the support of the genitourinary tract is instead provided by a variety of fascial layers, muscular tissues, ligaments, and/or tendons within the pelvis. Hence, the treatment of the present invention may be directed at a variety of tissue structures defining the pelvic floor and/or diaphragm (including: anterior sacro-coccygeal ligament; arcus tendineus fasciae pelvis ATRP, the white line of the pelvis; fasciae of the obturator ~~internus~~ internus muscle; the arcus tendineus levator ani or "picket fence" to the iliococcygeus portion of the levator ani muscle; bulbocavernosus muscle; ischiocavernosus muscle; urethrovaginal sphincter; m. compressor urethrae muscle; and m. sphincter urethrovaginal muscle which replaces deep perineal muscle); structures of the bladder and urethra (including: urethrovesical fascia; detrusor muscle; and the pubo-coccygeus muscle which relaxes to open the bladder neck, initiating micturation); structures of the vagina (including: vagino-uterine fascia, lamina propria-the dense connective tissue layer just under the epithelium; pubo-urethral or puboprostatic ligaments; pubo-vesicle ligament and posterior pubo-urethral or puboprostatic ligament; pubovesicle muscle, a smooth muscle that is integrated with the pubovesicle ligament; and pubocervical fascia which attaches to the ATRP); structures of the uterus (including: round ligament; sacrouterine ligament; and broad ligament); and structures of the bowel (including: rectal fascia and mackenrodt's ligament).

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Please replace paragraph [0051] with the following amended paragraph:

[0051] Referring now to Figs. 3A-3C, a heat applying probe 10 comprises a probe body having a sheath component 12 and an electrical rod component 14. The electrode rod 14 is ~~reciprocatably~~ reciprocately mounted in a lumen of sheath 12 so that a distal electrode array 16 on the rod 14 may be retracted and extended into and from the distal end 18 of sheath 12. A proximal handle 20 is provided on the sheath, and a proximal connector 22 is provided on the electrode rod component 14. Electrode array 16, as illustrated, may optionally include four individual tissue-penetrating electrode tips 24, with each tip having a sharpened distal end suitable for penetrating into tissue, particularly for transmucosal penetration through the vaginal wall and into the tissue structures which support the urethra, urinary sphincter, bladder neck, and the like. In other embodiments, between two and twenty tissue-penetrating electrodes might be used as shown in Fig. 3B. It will be appreciated that the above depictions are for illustrative purposes only and do not necessarily reflect the actual shape, size, or dimensions of the probe 10. This applies to all depictions hereinafter.

Please replace paragraph [0056] with the following amended paragraph:

[0056] Direct probe 42 ~~will~~ may optionally be used in a laparoscope procedure using a superior approach, typically under the direction of a laparoscope 50 inserted near the patient's mid-line (for example, adjacent the belly button). Handle 46 is manipulated so as to "paint" bipolar electrode 36 across the endopelvic fascia surface until the target region has been sufficiently heated. Alternative surgical methods for use of related probes may access the endopelvic fascia using an inferior approach, preferably with a small transvaginal incision as illustrated in Fig. 2.

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Please replace paragraph [0057] with the following amended paragraph:

[0057] Figs. 6 and 6A illustrate alternative cooled electrode vaginal probes for indirect treatment of tissue to inhibit incontinence through an intervening or intermediate tissue, which may comprise a spared zone or safety zone where tissue necrosis is inhibited. In these embodiments, a vaginal probe body 54 includes a plurality of electrodes 56 which are cooled by fluid conduits 58. The fluid conduits cool the intervening or intermediate tissue between probe body 54 and the endopelvic fascia RF, such as the vaginal wall VW as seen in Fig. 6. The probe body between electrodes 56 also cools the intervening tissue. Once the intervening tissue of the vaginal wall VW (and optionally, the urethra, bladder neck, and bladder) are cooled sufficiently, RF current is transmitted between the electrodes of the probe body to heat the endopelvic fascia. Advantageously, the pre-cooling can inhibit heating of the intervening tissue to a temperature causing surface lesions within the vagina. Feedback on the pre-cooling and heating temperatures may be provided by needle-mounted temperature sensors 62 which may optionally be ~~reciprocatably~~ reciprocately ~~advancable~~ from probe body 54 through a sensor port 64. A relatively flat tissue-engaging electrode surface helps direct electrical current flux 60 toward the endopelvic fascia, while electrically insulating film disposed over at least a portion of electrodes 56 near an adjacent electrode may inhibit edge-induced flux concentration. Exemplary cooled electrode structures are described in more detail in U.S. Patent No. 6,283,987 entitled Ribbed Electrodes and Methods for Their Use (Attorney Docket No. 17761-00710US), the full disclosure of which is incorporated herein by reference. As can be understood by comparison of Figs. 6 and 6A, the electrodes may extend axially along a length of the probe body, or may each have a conductive surface which is elongated in the lateral orientation, with probe bodies having more than two electrodes preferably utilizing bipolar RF energy between alternating pairs of the electrodes.

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Please replace paragraph [0059] with the following amended paragraph:

[0059] Referring to Figs. 7B-7C, once the axial position of the centroid or sphincter for the urethra is identified, it may be possible to generate a ~~palpatable~~ palpatory marker for axial registration of the treatment zone as shown. Specifically, a radially distensible urethral guide tube 80 may house first and second actuation rods 82, 84, with the second rod here being in the form of a tube in which the first rod is disposed. Distal bodies at the distal ends of the first and second actuation rods 82, 84 expand the distendable tube when aligned as illustrated in Fig. 7C. Expanded portion 86 may be identified by finger F of the physician through the vaginal wall.

Please replace paragraph [0073] with the following amended paragraph:

[0073] To avoid injury to nerves in the bladder neck region while providing sufficient treatment volume along the endopelvic fascia, it may be advantageous to distribute the treatment volume along the patient's lateral orientation while limiting the length of treatment along the axis of the patient's urethra. This may minimize exposure of the bladder neck and antero-lateral vaginal wall nerves to RF energy. Such a laterally elongate elongated treatment region of the endopelvic fascia will preferably be significantly wider (along the medial- lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15 mm. Treatment depths will preferably be at least about 2 mm, optionally being as much as 6 mm.

Please replace paragraph [0084] with the following amended paragraph:

[0084] Referring now to Fig. 23, the development of treatment volume at a temperature of above 70°C (left legend) as a function of dwell time is graphically illustrated. A non-invasive cooled electrode probe similar to that shown in Figs. 6 and 6A heats tissue until the temperature sensing needle at 4.5 mm depth reaches a set point of 75°C at 185 seconds. Following this set point, the RF energy is lowered and a dwell time of 45 seconds ~~[[in]]~~ is maintained. The RF

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energy is then turned off at 230 seconds. The heat then remains for about 15 seconds after this point, to about 245 seconds. If the RF energy was turned off at the set point 185 seconds (i.e., no dwell time), the treatment volume of tissue above 70°C between about 170 and 200 seconds would have been less than 70 cubic millimeters. In contrast, as shown in Fig. 23, the treatment volume of tissue above 70°C between about 215 and 245 seconds is greater than 300 cubic millimeters, a four-fold increase over heating with no dwell period. Hence, dwell periods may play an important role in achieving increased treatment tissue volume.